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No. 05-1583

In the Supreme Court of the United States

IMPAX LABORATORIES, INC.,
Petitioner,

v.

ASTRAZENECA AB, AKTIEBOLAGET HÄSSLE, KBI-E INC., KBI INC. and ASTRAZENECA LP,
Respondent.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

REPLY BRIEF OF PETITIONER

JEFFREY J. TONEY
Counsel of Record
JOHN L. NORTH
WILLIAM F. LONG
SUTHERLAND ASBILL & BRENNAN LLP
999 PEACHTREE STREET
ATLANTA, GA 30309
(404) 853-8000

Counsel for Petitioner
Impax Laboratories, Inc.

Becker Gallagher Legal Publishing, Inc. 800.890.5001

LIST OF PARTIES TO THE PROCEEDING PURSUANT TO RULES 14.1(b) AND 29.6

Petitioner Impax Laboratories, Inc. certifies that the names of all parties to this proceeding appear in the caption of this Petition for Writ of Certiorari.

Petitioner has no parent corporation, and no publicly held company owns 10% or more of its stock.

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The present case presents a better case for Supreme Court review than the recent petition of *Technology Licensing*. In *Technology Licensing*, the Federal Circuit held that the plaintiff had voluntarily waived the right to a jury. No waiver exists in the present case. Moreover, the outcome of the present case will affect the rights of generic pharmaceutical companies to get their competing products to market. The petition is not moot, as it presents an issue "capable of repetition, yet evading review."

Rather than eliminate confusion, the *Technology Licensing* opinion will cause more confusion because it could not and did not overrule prior inconsistent Federal Circuit caselaw, and contrary to Astra's argument, has put the Federal Circuit in conflict with the other circuits.

Astra does not dispute that the only 18th Century judicial proceeding that could invalidate a patent was the writ of *scire facias*. Astra's other arguments are irrelevant under this Court's historical analysis. In sum, Astra has provided no sound reason for denying Impax's petition.

I. THE PRESENT CASE PRESENTS A BETTER CASE FOR SUPREME COURT REVIEW THAN *TECHNOLOGY LICENSING*

The present case presents a significantly better case for this Court's review than *In re Technology Licensing*, 423 F.3d 1286 (Fed. Cir. 2005), *cert. denied*, 2006 WL 1519374, (U.S. Jun 05, 2006) because the *Technology Licensing* facts were clouded by an issue of waiver. The Federal Circuit found that *Technology Licensing* had "voluntarily abandoned" its right to a jury trial. *Id.* at 1289-90.

The Federal Circuit and the District Court are attempting to extend the *Technology Licensing* holding to the facts of present case, notwithstanding that the present case includes no issue of waiver. The District Court expressly found that

Impax had not waived its right to a jury, 12a-13a and the Federal Circuit agreed: "Impax timely asserted a demand for a jury trial." 6a.

The present case presents a better case for the Court's review than *Technology Licensing* for the additional reason that it involves the right of generic pharmaceutical companies to get competing products to market under the Hatch-Waxman Act. Protecting the rights of generic drug companies presents an issue that is of exceptional importance to the well-being of this nation. *See generally* Wendy H. Schacht & John R. Thomas, *The Hatch-Waxman Act: Legislative Changes In The 108th Congress Affecting Pharmaceutical Patents*, CRS Report RL 32377 (2004). Moreover, unlike other patent cases, generic drug cases filed initially under 35 U.S.C. § 271(e) present a class of cases in which this precise issue arises with frequency because the patentee will frequently have the option of amending its initial complaint (which contains no damages claim) with a subsequent claim for damages, as was the situation in the present case. *See, e.g., Sanofi-Synthelabo v. Apotex Inc.*, No. 02- Civ. 2255 RWS, 2002 WL 1917871 (S.D.N.Y. Aug. 20, 2002); *Warner-Lambert Co. v. Purepac Pharmaceutical Co.*, No. Civ. A. 98-2749 (JCL), 2001 WL 883232 (D.N.J. March 30, 2001); *Hoechst Marion Roussel, Inc. v. Par Pharmaceutical, Inc.*, Civ. No. 95-3673 (DRD), 1996 WL 468593 (D.N.J. March 14, 1996); *Pfizer Inc. v. Novopharm Ltd.*, No. 00 C 1475, 2001 WL 477163 (N.D. Ill. May 3, 2001); *Glaxo Group Ltd. v. Apotex, Inc.*, No. 00 C 5791, 2001 WL 1246628 (N.D. Ill. Oct. 16, 2001).

II. THE PETITION IS NOT MOOT

Contrary to Astra's argument, Astra's Brief in Opposition ("Astra Opp.") at 2, 26-27, the petition is not moot, as no final judgment has been entered below. Moreover, if and

when entered, final judgment will not moot the issue, as this case presents the precise situation which is "capable of repetition yet evading review." *First National Bank of Boston v. Bellotti*, 435 U.S. 765, 774 (1978). A case is not mooted when (1) the challenged action was in its duration too short to be fully litigated prior to its cessation nor expiration, and (2) there is a reasonable expectation that the same complaining party will be subjected to the same action again. *Id.* at 774-775; *Meyer v. Grant*, 486 U.S. 414, 417 n.2 (1988). Both elements are satisfied in the present case.

The challenged action is the wrongful striking of Petitioner's jury demand. Petitioner followed the preferred procedure for challenging that action, namely, filing a petition for a writ of mandamus. *See Beacon Theatres, Inc. v. Westover*, 359 U.S. 500, 511 (1959); *Dairy Queen, Inc. v. Wood*, 369 U.S. 469, 472 (1962). This Court has repeatedly approved the use of mandamus as the appropriate vehicle for correcting a wrongfully stricken demand for a jury, because waiting until after a final judgment cannot undo the harm to the requesting party. *In re Simons,* 247 U.S. 231, 239-240 (1918). When the district court and court of appeals refuse to stay the trial pending this Court's review – and the *Technology Licensing* opinion now provides a strong disincentive for a district court to stay a trial pending review – a proceeding seeking a writ of mandamus provides insufficient time for this Court to consider the issue.

More than a reasonable expectation exists that Impax will be subjected to the wrongful denial of a right to a jury trial again. Impax is a generic drug company. Hence, practically every time it files an Abbreviated New Drug Application, it will be sued for infringement by the name-brand drug manufacturer under 35 U.S.C. § 271(e). The initial suit cannot include a claim for damages, but as is typically the case, Impax will receive approval to market its drug before

the infringement suit has been adjudicated. Impax and its customers will be faced with the threat of a damages suit, and the name-brand pharmaceutical company can exercise the same tactics as Astra in the present case by, for example, suing to recover damages from Impax's customers but seeking only injunctive relief directly from Impax, and thereby wrongfully denying Impax a jury.

Contrary to the implication of Astra's arguments, a petition requesting review of an order denying a writ of mandamus does not impose a higher standard of review. *See, e.g., Schlagenhauf v. Holder,* 379 U.S. 104 (1964) (reviewing denial of mandamus); *see also La Buy v. Howes Leather Co.,* 352 U.S. 249 (1957) (reviewing grant of mandamus). This Court should consider and decide the issue now.

III. THE *TECHNOLOGY LICENSING* OPINION DID NOT ELIMINATE CONFUSION

Astra's position is, in essence, that the *Technology Licensing* opinion has eliminated the confusion caused by the Federal Circuit's conflicting opinions. *See, e.g.,* Astra's Opp. at 10-11. That argument might carry some weight if *Technology Licensing* had overruled *In re Lockwood,* 50 F.3d 966 (Fed. Cir. 1995) (patentee entitled to jury trial on counterclaim of invalidity notwithstanding that damages claim had been dismissed) and the other Federal Circuit opinions inconsistent with *Technology Licensing*. But the *Technology Licensing* panel did not even have the power to overrule *Lockwood,* and in any event, expressly *approved Lockwood. Technology Licensing,* 423 F.3d at 1288 n.1.

District courts now will be required to sort out the Federal Circuit's inconsistent opinions, which is certain to result in misapplication of this Court's Seventh Amendment case law. As noted in Impax's Petition, the *Technology Licensing*

court's attempt to reconcile its opinion with *Lockwood* puts the Federal Circuit in direct conflict with the other circuits on whether a dismissed claim is relevant to determining the right to a jury trial, a conflict which Astra refuses even to acknowledge. Astra Opp. at 8. *Technology Licensing* is certain to cause only more confusion rather than resolving any confusion.

For example, the district court in *O2 Micro International Ltd. v. Monolithic Power Systems,* 399 F. Supp. 2d 1064, 1087-88 (N.D. Cal. 2005) found that a jury could not be treated as merely advisory on a counterclaim of invalidity when a party demanded a jury, notwithstanding that the patentee's damages claim had been dismissed via summary judgment. The *O2 Micro* court believed that, under *Technology Licensing,* the *dismissed* damages claim (as opposed to the counterclaim of invalidity) gave rise to a right of jury trial. *Compare with In re Evangelist,* 760 F.2d 27, 32 (1st Cir. 1985) (claim for damages dismissed on summary judgment not relevant when determining party's asserted Seventh Amendment right to a trial by jury); *Hildebrand v. Board of Trustees,* 607 F.2d 705, 710 (6th Cir. 1979) (accord). Astra's arguments that *Technology Licensing* has resolved any district court confusion and that the opinion does not conflict with the other circuits are meritless.

IV. THE *TEGAL* CASE DID NOT INVOLVE A DECLARATORY JUDGMENT COUNTERCLAIM

Astra's reliance upon *Tegal v. Tokyo Electron America, Inc.*, 257 F.3d 1331 (Fed. Cir. 2001) is misplaced. Astra Opp. at 13-14. The accused infringer in *Tegal* filed only an affirmative defense of invalidity; it did not file a counterclaim seeking a declaratory judgment of invalidity. *Tegal*, 257 F.3d at 1338, 1339.

Nevertheless, *Tegal* further undermines Astra's argument that *Technology Licensing* resolved any confusion existing in Federal Circuit Seventh Amendment jurisprudence. The *Tegal* court emphasized that *Lockwood's* holding (*i.e.*, that the accused infringer's counterclaim of invalidity was triable to a jury notwithstanding that the patentee's damages claim had been dismissed before trial) did not apply when the accused infringer asserted only affirmative defenses and no counterclaim. The *Tegal* court was careful to distinguish the situation in which the accused infringer had asserted no counterclaim: "this court holds that a defendant, asserting only affirmative defenses and *no counterclaims*, does not have a right to a jury trial in a patent infringement suit if the only remedy sought by the plaintiff-patentee is an injunction." *Id.* at 1341 (emphasis supplied).

V. RESPONDENT DOES NOT DISPUTE THAT THE ONLY 18TH CENTURY CIVIL PROCEEDING THAT COULD INVALIDATE A PATENT WAS THE COMMON LAW WRIT OF *SCIRE FACIAS*

Astra does not dispute that the writ of *scire facias* was the only 18th century English judicial proceeding that could be used by an accused infringer to invalidate a patent. Astra does not deny that the *relief sought* in the modern counterclaim is identical to the relief sought in the 18th century writ of *scire facias*. Instead, Astra attempts to raise other arguments that are irrelevant under this Court's historical analysis.

A. Astra requests the Court to compare a modern reexamination proceeding before the PTO, a non-judicial proceeding, with the writ of *scire facias*. Astra Opp. at 22-23. Astra's proposed comparison is entirely irrelevant. The fact that a modern reexamination proceeding and the 18th century writ of *scire facias* both could be used to invalidate a patent does not change the fact that writ of *scire facias* is the

best analog to the modern declaratory judgment action of invalidity.[1] This Court's historical test requires identifying the closest 18th century analog with the claim and relief requested in the case at issue, not with some other proceeding not even at issue in the case.

B. Astra's argument that the standing requirement under the 18th century writ of *scire facias* was broader than the modern declaratory judgment counterclaim, Astra Opp. at 24-25, even if true, is similarly irrelevant. Astra tacitly admits that an 18th century competitor threatened with an infringement suit could initiate a writ of *scire facias* proceeding. Hence, the nature of the writ of *scire facias* encompassed precisely the nature of the modern declaratory judgment action to invalidate a patent. Whether the writ of *scire facias* was available to a broader class of litigants than the modern action is not relevant. The important point is that *scire facias* provided a cause of action to at least the same class of litigants as the modern declaratory judgment action to invalidate a patent.

C. Astra suggests incorrectly that all writs of *scire facias* were tried in courts of chancery. Astra Opp. at 21. In fact, *scire facias* proceedings to invalidate patents were ultimately tried in common law courts. *See, e.g., King v. Else,* 1 Carp. P.C. 103, Dav. Pat. Cas. 144 (K.B. 1785), and *King v. Arkwright,* 1 Carp. P.C. 53 (K.B. 1785). Both *Else* and *Arkwright* were tried before the King's Bench, an English common law court. The *Arkwright* case was tried before Judge Mansfield, one of the most famous common law judges of the late 18th century. *See, generally,* 1 J. Oldham, *The*

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[1] Of course, the modern declaratory judgment counterclaim is much more similar to the writ of *scire facias*, because, for example, both are judicial proceedings.

Mansfield Manuscripts and the Growth of English Law in the 18th Century (1992). Indeed, a "writ" was the procedure to initiate an action at law, as opposed to a "bill" which was the procedure to initiate a proceeding in equity. P. Devlin, *Jury Trial of Complex Cases: English Practice at the Time of the Seventh Amendment*, 80 Colum. L. Rev. 43, 57, 58 (1980). It is true that the chancery courts had great power, and the jurisdiction of the common law courts has been described as "any suit which the Lord Chancellor ... would permit to be tried in the [common law courts]." *Id.* at 45. Some legal causes of action would be filed with the court of chancery, but if the court deemed it a legal cause of action rather than an equitable cause, it would refer the action to the common law courts, and if necessary, invent a new writ to provide the plaintiff with a means to proceed before a court of law. *Id.* at 49. The only mode of trial available to a common law court was a trial by jury. *Id.* at 44.

D. Astra denies the independent nature of a counterclaim seeking a declaratory judgment of patent invalidity. Astra Opp. at 18-19, 25 n.6. Contrary to Astra's argument, the fact that such a claim may not be asserted unless there is at least a threat of suit by a patentee does not diminish the independent nature of the declaratory judgment action seeking invalidity. *Cardinal Chemical Co. v. Morton Int'l, Inc.*, 508 U.S. 83, 96 (1993). Such a declaratory judgment claim may be asserted without regard to whether the patentee actually files suit, and the court would retain jurisdiction to adjudicate the claim even if the patentee did not file a counterclaim of infringement or if the patentee's claim of infringement is dismissed. *See Fort James Corp. v. Solo Cup Co.*, 412 F.3d 1340, (Fed. Cir. 2005) (court maintains jurisdiction of declaratory judgment counterclaim to invalidate a patent unless patentee covenants not to sue for past, present and future infringement). Astra's argument that the accused

infringer loses its standing to litigate a counterclaim of invalidity if the patentee withdraws its infringement allegations is false, except in the circumstance (not present in this case) when the patentee covenants not to sue for past, present or future infringement. *Id.; accord Super Sack Manufacturing Corp. v. Chase Packaging Corp.*, 57 F.3d 1054, 1059-60 (Fed. Cir. 1995).

E. Astra's argument based upon modern pleading rules that require the joinder in one suit of any infringement claim with a declaratory judgment claim of invalidity is also without merit. Astra Opp. at 25. Indeed, this argument has already been considered and rejected by this Court. *See Ross v. Bernhard*, 396 U.S. 531, 538 (1970) (the "Seventh Amendment question depends on the nature of the issue to be tried rather than the character of the overall action"); *Beacon Theatres,* 359 U.S. at 510 ("the availability of declaratory judgment or joinder in one suit of legal and equitable causes" cannot be used as a basis to deny the right of jury trial on legal issues). The fact that a suit for infringement is a compulsory counterclaim under modern pleading procedures does not affect the nature of the analysis: whether the declaratory judgment counterclaim asserts legal rather than equitable relief.

Even if the modern counterclaim seeking to have a patent invalidated can be properly characterized as "sui generis," it would not diminish the parties right to a jury trial. "The [Seventh] Amendment requires trial by jury in actions unheard of at common law." *Tull v. United States*, 481 U.S. 412, 420 (1987).

F. Astra also implies, incorrectly, that the remedy of damages is always the test for a right to a jury. Astra Opp. at 13. To be sure, if damages are sought, then a right to a jury attaches. But this Court has emphasized that if the

remedy sought, whether it be damages or some other remedy, was available in the late 18th century England only in a court of law, then the parties are entitled to a jury trial on demand. *Tull v. United States*, 481 U.S. 412, 421-422 (1987) (because a civil penalty was a type of remedy at common law that could only be enforced in courts of law, the parties were entitled to a jury trial on demand). Although the existence of damages in a case clearly gives right to a jury, the lack of a demand for damages hardly proves that no jury right exists. Numerous legal causes of action exist that entitle the parties to a jury that do not involve a demand for damages. *See, e.g., Pernell v. Southall Reality*, 416 U.S. 363, (1974) (action to recover possession of real property entitled to a jury trial because it was a common law remedy under 18th century procedure). In *Pernell*, the relief requested constituted a demand for legal relief, and the parties were therefore entitled to a jury on demand. Petitioner's demand to invalidate Respondent's patent constitutes a demand for legal relief, and therefore entitles the parties to a jury. The absence of a demand for damages is not relevant given the legal nature of Petitioner's demand.

CONCLUSION

The right to a jury trial is one of the most important rights guaranteed by our Constitution. Astra has provided no argument to rebut the reasons for granting certiorari outlined in Impax's Petition. Impax respectfully submits that the Court should grant Impax's petition for a writ of certiorari.

Respectfully submitted,

Jeffrey J. Toney
Counsel of Record
John L. North
William F. Long
Sutherland Asbill & Brennan LLP
999 Peachtree Street
Atlanta, Georgia 30309
(404) 853-8000

Attorneys for Petitioner Impax Laboratories, Inc.